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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/069,574 | 08/01/2002 | Gerard Ribes | 1721-49 | 1529 |

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

| EXAMINER | |
|---|---|
| WEDDINGTON, KEVIN E | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/069,574 | RIBES ET AL. | |
| | Examiner | Art Unit | |
| | Kevin E. Weddington | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5-10 and 12-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-10 and 12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-28-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-3, 5-10 and 12-23 are presented for examination.

The allowance of claims 1-3, 5-10 and 12-23 is removed so that a new rejection can be made.

Applicants' amendment filed September 28, 2005 has been received and entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-10, 12, 13, 15, 16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauvaire et al., "4-hydroxyisoleucine: A Novel Amino Acid Potentiator of Insulin Secretion", Diabetes, 1998, Vol. 47, No. 2, pp. 206-210.

Sauvaire et al. teach 4-hydroisoleucine as a well-known agent that potentiates insulin secretion and possesses antidiabetic activity (see the abstract). Note the 4-hydroisoleucine potentiate insulin secretion which means the agent increases and induces insulin release. Note the applicants' method to induce an insulin sensitizing or insulin mimetic effects with the administration of 4-hydroxyisoleucine is achieved since insulin sensitizing causes the body to be sensitive to insulin and the administration of 4-hydroxyisoleucine would inherently achieved this effect. As to the reduction of phosphatase activity associated with the signaling route of the insulin receptor, and/or stimulated PI 3-kinase activity on IRS-1 and/or IRS-2 is anticipated

by 4-hydroxyisoleucine since the said mechanism is associated with diabetes and the product of identical chemical composition cannot have mutually exclusive properties (See In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1644, 1658 (Fed. Cir 1990)). As to claim 5, the racemate 4-hydroxyisoleucine contains both the R and S isomer, therefore, the isomers posses the antidiabetic properties. The disorders or conditions disclosed in claims 6-10 and 12 would be inherently treated with the administration of 4-hydroxyisoleucine since the said disorders or conditions are complications associated with diabetes.

Claims 1-3, 5-10, 12, 13, 15, 16 and 23 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauvaire et al., (Diabetes, (1998) 47(2), pp. 206-210) in view of Windholz et al., THE MERCK INDEX, Tenth Edition, 1983, pp. 723 and 724, abstract no. 4866.

Sauvaire et al. was discussed above supra teaches 4-hydroxyisoleucine as having antidiabetic activity to treat to diabetes.

The instant invention differs from the cited reference in that the cited reference does not teach the addition of insulin. However, the secondary reference, Windholz et al., teaches insulin as a well-known antidiabetic agent. Clearly, one skilled in the art would have assumed the combination of two individual antidiabetic agents into a single composition would give an additive effect in the absence of evidence to the contrary.

With respect to claim 14, the kit comprising both insulin and 4-hydroxyisoleucine from the cited references, one of skill in the art would have had the claimed kit and composition based upon the teachings of the combined references as set above supra. The combined references teach using the agents together for the same formulation (purpose) that would have been found in the claimed composition and/or kit to formulate composition into a kit format because the claimed kit is tailored for use or kit formulation comprising the composition claimed. Hence, it would have been obvious to package the composition required for the method into kit format of the well-known commercial expediency of doing so. Further, the fact that

an old compound, packaged and labeled to show its (new?) use is not patentable. See In re Haller, 73 USPQ 403 CCPA 1946.

The instant invention differs from the cited references in that the cited references do not teach the timing of the administration of 4-hydroxyisoleucine. However, the timing of administration of the 4-hydroxyisoleucine is an art-recognized result-effective variable and it would have been obvious to one skilled in the art to modify it in the method of the cited reference to achieve the desired effectiveness of the agent.

To formulate 4-hydroxyisoleucine into a capsule or a tablet is a well-known in the art for oral administration.

Claims 14 and 17-22 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
November 3, 2005